IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
ÅKERLUND, Roger

Serial No.: 10/063,159

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For: METHOD AND ASSEMBLY FOR FLUID TRANSFER AND DRUG CONTAINMENT IN AN INFUSION SYSTEM

Group Art Unit: 3767

Examiner: SCHELL, LAURA C.

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Commissioner for Patents
P.O. Box 1450
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RESPONSE TO NON-FINAL OFFICE ACTION

INTRODUCTORY COMMENTS:

The following amendments and remarks are provided in response to the Non-Final Office Action dated March 22, 2006.

AMENDMENTS TO THE CLAIMS:

Please amend claims 1-49 as follows:

1. (Original) A fluid transfer assembly for use in an infusion system, said assembly comprising: a fluid container having an infusion fluid, a drug container having a medical substance, at least one fluid barrier controlling fluid passage between said drug container and said fluid container, said fluid container further comprising at least one inlet port for receiving said medical substance from said drug container, said drug container further comprising a cap for sealing said drug container, said at least one inlet port further comprising a first luer-lock connector, and said cap further comprising a second luer-lock connector for attachment to said first luer-lock connector, wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage.

2. (Withdrawn) The fluid transfer assembly according to claim 1, said at least one inlet port further comprising a first fluid duct between said fluid container and said first luer-lock connector, wherein said fluid barrier is provided inside said first fluid duct.

3. (Original) The fluid transfer assembly according to claim 1, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, wherein said fluid barrier is provided inside said second fluid duct.

4. (Withdrawn) The fluid transfer assembly according to claim 1, said inlet port further comprising a first fluid duct between said fluid container and said first luer-lock connector, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, and that fluid barriers are provided both inside said first and said second fluid ducts.

5. (Withdrawn) The fluid transfer assembly according to claim 1, wherein the second luer-lock connector is attached directly to said cap.

6. (Withdrawn) The fluid transfer assembly according to claim 1, wherein the second luer-lock connector is an integral part of said cap.

7. (Withdrawn) The fluid transfer assembly according to claim 1, said second luer-lock connector further comprising a removable closure for protection before use.

8. (Original) The fluid transfer assembly according to claim 1, said second luer-lock connector further comprising a pierceable closure for protection before use.

9. (Original) The fluid transfer assembly according to claim 1, said drug container further comprising a neck, and said cap further comprising locking members for grasping said neck.

10. (Original) The fluid transfer assembly according to claim 1, said drug container further comprising an opening sealed by a closure, and said cap further comprising a hollow needle for penetrating said closure.

11. (Withdrawn) The fluid transfer assembly according to claim 1, said drug container further comprising a neck, and said cap further comprising a protruding member attachable to said neck by an annular capsule member.

12. (Original) The fluid transfer assembly according to claim 1, said drug container further comprising a neck, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, and said cap further comprising locking members for grasping said neck.

13. (Original) The fluid transfer assembly according to claim 1, said fluid barrier further comprising a brittle polymer member dividable along a weakening line by said external force.

14. (Withdrawn) The fluid transfer assembly according to claim 1, said walls of said inlet port being made of a flexible material and forming a first fluid duct between said fluid container and said first luer-lock connector, said fluid transfer assembly further comprising a first clamping member able to compress said walls thereby closing said first fluid duct and preventing undesired fluid passage between said fluid container and said first luer-lock connector.

15. (Original) The fluid transfer assembly according to claim 1, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, said fluid transfer assembly further comprising a second clamping member for compressing said protruding member, thereby closing said second fluid duct and preventing undesirable fluid passage between said second luer-lock connector and said drug container.

16. (Original) The fluid transfer assembly according to claim 1, said fluid container further comprising a protruding, resilient tube, said first luer-lock connector of said at least one inlet port being provided on a hollow spike member able to be firmly retained inside said tube.

17. (Original) The fluid transfer assembly according to claim 1, said at least one inlet port, in addition to said first luer-lock connector, further comprising an infusion line attached thereto, and said fluid transfer assembly further comprising a third clamping member for compressing said infusion line, thereby preventing undesirable fluid passage there through.

18. (Withdrawn) The fluid transfer assembly according to claim 1, said at least one inlet port comprising a first fluid duct between said fluid container and said first luer-lock connector, wherein said fluid barrier is provided inside said first fluid duct, said fluid container being flexible and comprising a first polymer material, said first fluid duct being formed by walls comprising a second polymer material, said first luer-lock connector comprising a third polymer material, and said fluid barrier comprising a fourth polymer material, wherein said first and second polymer materials are more flexible than said third polymer material, and said fourth polymer material is more brittle than all of said first, second and third polymer materials.

19. (Original) The fluid transfer assembly according to claim 1, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, said fluid barrier being provided inside said second fluid duct, said drug container comprising a rigid material, said protruding member comprising a more flexible material than said second luer-connector and said drug container, and said fluid barrier comprising a more brittle material than said drug container, said protruding portion, and said second luer-lock connector.

20. (Original) The fluid transfer assembly according to claim 1, wherein the composition of said drug container is selected from the group consisting of glass and a rigid polymer material.

21. (Original) A drug container for use in an infusion system, said drug container comprising: a fixed dose of a medical substance, and a cap for sealing said drug container, said cap further comprising a luer-lock connector for attachment to a corresponding connector provided on an inlet port of a container for infusion fluid, thereby creating a luer-lock coupling.

22. (Withdrawn) The drug container according to claim 21, said cap further comprising a protruding member forming a fluid duct between said drug container and said second luerconnector, wherein fluid barrier able to be ruptured by an external force is provided inside said second fluid duct.

23. (Withdrawn) The drug container according to claim 21, wherein said luer-lock connector is attached directly to said cap.

24. (Withdrawn) The drug container according to claim 21, wherein said luer-lock connector is integral with said cap.

25. (Withdrawn) The drug container according to claim 21, further comprising a removable closure for protecting said second luer-lock connector.

26. (Original) The drug container according to claim 21, further comprising a pierceable closure for protecting said second luer-lock connector.

27. (Original) The drug container according to claim 21, said drug container further comprising a neck, and said cap further comprising locking members for grasping said neck.

28. (Original) The drug container according to claim 21, said drug container further comprising an opening sealed by a closure, and said cap further comprising a hollow needle for penetrating said closure.

29. (Withdrawn) The drug container according to claim 21, said drug container further comprising a neck, and said cap further comprising a protruding member able to be attached to said neck by an annular capsule member.

30. (Original) The drug container according to claim 21, said drug container further comprising a neck, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, and said cap further comprising locking members for grasping said neck.

31. (Original) The drug container according to claim 21, said cap further comprising a protruding member encircling a fluid barrier of a brittle polymer member, said barrier able to be divided along a weakening line by an external force.

32. (Original) The drug container according to claim 21, said cap further comprising a protruding member forming a fluid duct between said drug container and said luer-lock connector, wherein a fluid barrier is provided inside said fluid duct, said drug container comprising a rigid material, said protruding member comprising a more flexible material than said luer-lock connector and said drug container, and said fluid barrier is made of a more brittle material than said drug container, said protruding portion, and said luer-lock connector.

33. (Original) The drug container according to claim 21, wherein said drug container is made from the group consisting of glass and a rigid polymer material.

34. (Withdrawn) A method for enabling fluid transfer in an infusion system, said method comprising the steps of: providing a fluid container having an infusion fluid and a drug container having a medical substance, said fluid container comprising at least one inlet port for receiving said medical substance from said drug container, providing said infusion system with at least one fluid barrier for controlling fluid passage between said drug container and said fluid container, providing said fluid container with a first luer-lock connector on said inlet port, providing said drug container with a cap comprising a second luer-lock connector, attaching said first luer-lock connector to said second luer-lock connector by a luer-lock coupling, applying an external force onto said fluid barrier, thereby opening said fluid passage, creating a positive pressure inside said fluid container, transferring at least part of said positive pressure to said drug container via said fluid passage, and removing said positive pressure from said fluid container, thereby initiating transfer of said medical substance from said drug container to said fluid container.

35. (Withdrawn) The method according to claim 34 further comprising the step of rupturing said fluid barrier by twisting, bending, or squeezing material portions between said fluid container and said first luer-lock connector.

36. (Withdrawn) The method according to claim 34 further comprising the step of rupturing said fluid barrier by twisting, bending or squeezing material portions between said drug container and said second luer-lock connector.

37. (Withdrawn) The method according to claim 34 wherein said drug container further comprises a neck, and wherein said cap further comprises locking members, further comprising the step of causing said locking members to grasp said neck, thereby attaching said cap permanently to said drug container.

38. (Withdrawn) The method according to claim 34, wherein said drug container further comprises an opening sealed by a closure, and said cap further comprises a hollow needle, further comprising the step of penetrating said closure with said hollow needle.

39. (Withdrawn) The method according to claim 34 further comprising the steps of: protecting the second luer-lock connector by a removable closure, and removing said closure before attaching said second luer-lock connector to said first luer-lock connector.

40. (Withdrawn) The method according to claim 34 further comprising the steps of: protecting said second luer-lock connector by a pierceable closure, and piercing said closure when attaching said second luer-lock connector to said first luer-lock connector.

41. (Withdrawn) The method according to claim 34, wherein said drug container further comprises a neck, and wherein said cap further comprises a protruding member, further comprising the steps of providing an annular capsule member, and attaching said protruding member to said neck by means of said annular capsule member in a drug container filling line.

42. (Withdrawn) The method according to claim 34, wherein said fluid barrier further comprises a brittle polymer member comprising at least one weakening line, further comprising the step of dividing said brittle polymer member along said weakening line by means of said external force.

43. (Withdrawn) The method according to claim 34, wherein said walls of said inlet port further comprise a flexible material, further comprising the steps of: forming a first fluid duct between said fluid container and said first luer-lock connector inside said flexible material, and providing a first clamping member and compressing said walls, thereby closing said first fluid duct and preventing undesirable fluid passage between said fluid container and said first luer-lock connector.

44. (Withdrawn) The method according to claim 34, wherein said cap further comprises a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, further comprising the steps of: providing a second damping member, and compressing said protruding member, thereby closing said second fluid duct and preventing undesirable fluid passage between said second luer-lock connector and said drug container.

45. (Withdrawn) The method according to claim 34, wherein said fluid container further comprises a protruding, resilient tube, further comprising the steps of: providing a hollow spike member exhibiting said first luer-lock connector, and inserting said hollow spike member into said resilient tube.

46. (Withdrawn) The method according to claim 34 further comprising the steps of: attaching an infusion line to said inlet port in addition to said first luer-lock connector, and providing a third clamping member for compressing said infusion line, thereby preventing undesirable fluid passage there through.

47. (Withdrawn) The method according to claim 34, wherein said fluid container comprises a flexible first polymer material, further comprising the steps of: forming walls of a second polymer material into a first fluid duct between said fluid container and said first luer-lock connector, wherein said first luer-lock connector further comprises a third polymer material, wherein said fluid barrier further comprises a fourth polymer material, arranging said fluid barrier inside said first fluid duct, selecting said first and second polymer materials to be more flexible than said third polymer material, and selecting said fourth polymer material to be more brittle than all of said first, second and third polymer materials.

48. (Withdrawn) The method according to claim 34, wherein said drug container further comprises a rigid material, and wherein said cap further comprises a protruding member, thereby forming a second fluid duct between said drug container and said second luer-lock connector, further comprising the steps of: accommodating said fluid barrier inside said second fluid duct, selecting a more flexible material for said protruding member than for said second luer-lock connector and said drug container, and selecting a more brittle material for said fluid barrier than for said drug container, said protruding portion, and said second luer-lock connector.

49. (Withdrawn) The method according to claim 34, further comprising the step of making said drug container from the group consisting of glass and a rigid polymer material.